

What is XTANDI? XTANDI is a prescription medicine used to treat men with prostate cancer that:

- no longer responds to a hormone therapy or surgical treatment to lower testosterone OR
- has spread to other parts of the body and responds to a hormone therapy or surgical treatment to lower testosterone
   OR
- has not spread to other parts of the body and responds to a hormone therapy or surgical treatment to lower testosterone, and who are at high risk of cancer spreading to other parts of the body

It is not known if XTANDI is safe and effective in females or children.

### **Select Safety Information**

XTANDI may cause serious side effects including seizure.

If you take XTANDI, you may be at risk of having a seizure. Avoid activities where a sudden loss of consciousness could seriously harm you or someone else. Tell your doctor right away if you lose consciousness or have a seizure.

### YOUR XTANDI JOURNEY STARTS HERE

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**XTANDI** Support Solutions® helps eligible patients find ways to pay for **XTANDI** 

Our dedicated access specialists are here to help. Call 1-855-8XTANDI (1-855-898-2634).



### **ABOUT XTANDI**

- Understanding advanced prostate cancer
- Four types of advanced prostate cancer
- How XTANDI may help
- How XTANDI works
- Taking XTANDI
- Tips for staying on track
- Maintaining a healthy routine
- Tips that may help manage some side effects
- Keeping an open line of communication



### UNDERSTANDING ADVANCED PROSTATE CANCER

### When prostate cancer is advanced, it can be treated but not cured

Unlike early-stage prostate cancer, which can sometimes be cured with treatment, advanced prostate cancer cannot be cured.

But the good news is that your doctor has ways to potentially help manage it over time, and one of those ways may be with XTANDI.

Read the next page to learn about the four types of advanced prostate cancer that can be treated with XTANDI. Ask your doctor if XTANDI is appropriate for your type of advanced prostate cancer.

### Your doctor can tell if your cancer is getting worse or spreading

He or she may look at some indicators like:

- Your prostate-specific antigen (PSA) level or PSA doubling time. How fast is it rising?
- Your scans. Do they show tumors getting bigger or new ones developing?

On pages 5-11, see how XTANDI helped with four types of advanced prostate cancer in clinical studies.

### **Select Safety Information**

**XTANDI** may cause serious side effects including Posterior Reversible Encephalopathy Syndrome (PRES). If you take XTANDI you may be at risk of developing a condition involving the brain called PRES. Tell your doctor right away if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, reduced eyesight, blurred vision or other visual problems. Your doctor will do a test to check for PRES.



### **FOUR TYPES OF ADVANCED PROSTATE CANCER**

### Which type of advanced prostate cancer do you have?

XTANDI is FDA-approved to treat these types of advanced prostate cancer.



### **Metastatic castration-sensitive prostate cancer (mCSPC)**

- The cancer has spread to other parts of the body
- The cancer responds to a hormone therapy or surgical treatment to lower testosterone



### **Metastatic castration-resistant prostate cancer (mCRPC)**

- The cancer has spread to other parts of the body
- The cancer no longer responds to a hormone therapy or surgical treatment to lower testosterone



### Non-metastatic castration-resistant prostate cancer (nmCRPC)

- The cancer has not spread to other parts of the body
- The cancer no longer responds to a hormone therapy or surgical treatment to lower testosterone



## Non-metastatic castration-sensitive prostate cancer (nmCSPC) with high risk of cancer spreading

- The cancer has not spread to other parts of the body
- The cancer responds to a hormone therapy to lower testosterone
- There is a high risk of the cancer spreading to other parts of the body

Ask your doctor for more information regarding your type of advanced prostate cancer. Please see Important Safety Information on pages 25-31 and click here for Patient Information and Full Prescribing Information for XTANDI.



### **HOW XTANDI MAY HELP**



## XTANDI in metastatic castration-sensitive prostate cancer (mCSPC)

### **XTANDI** was studied in men with advanced prostate cancer that:

- Was still responsive to hormone therapy or surgical treatment to lower testosterone
- **Had spread** to other parts of the body

This study included 1,150 men. It compared 574 men taking XTANDI with 576 men not taking XTANDI.

All men either continued hormone therapy or had surgery to lower testosterone during the study.

## In this study of mCSPC: XTANDI slowed advanced prostate cancer progression



- Men taking XTANDI had a 61% lower chance of their cancer progressing compared with men not taking XTANDI during the study. Progression was seen in 89 (15.5%) men in XTANDI + ADT,\* and 198 (34.4%) men in ADT alone
  - The median<sup>†</sup> length of time until the cancer got worse<sup>‡</sup> was not reached for XTANDI + ADT vs. 19 months for ADT alone
- Progression was defined as the cancer getting worse, as measured by scans, or if the patient died for any reason

### **Select Safety Information**

**XTANDI may cause serious side effects including allergic reactions.** Allergic reactions have happened in people who take XTANDI. Stop taking XTANDI and get medical help right away if you develop swelling of the face, tongue, lip or throat.



## In this same study in men with mCSPC: XTANDI helped men live longer (Overall Survival)



- XTANDI significantly improved overall survival§ by 34% vs. ADT alone. There were 154 (26.8%) deaths in XTANDI + ADT vs. 202 (35.1%) deaths in ADT alone
  - The median length of time patients lived after starting treatment was not reached for either treatment arm

In addition, patients receiving XTANDI had a 72% improvement in delaying the time before receiving the next cancer treatment, including chemo.

Individual results may vary.

Results may vary. Talk with your doctor about what this may mean for you.

### **Select Safety Information**

**XTANDI may cause serious side effects including heart disease.** Blockage of the arteries in the heart (ischemic heart disease) that can lead to death has happened in some people during treatment with XTANDI. Your doctor will monitor you for signs and symptoms of heart problems during your treatment. Call your doctor or go to the emergency room right away if you get chest pain or discomfort at rest or with activity or shortness of breath during your treatment with XTANDI.

<sup>\*</sup>ADT=androgen deprivation therapy (hormone therapy or surgical treatment to lower testosterone).

<sup>&</sup>lt;sup>†</sup>The median is not the average but the middle of a set of numbers.

<sup>\*</sup>The length of time from start of the cancer treatment until the cancer got worse, as measured by scans, or if the patient died for any reason.

<sup>§</sup>The average length of time patients are alive after the start of treatment.



## XTANDI in metastatic castration-resistant prostate cancer (mCRPC)

### **XTANDI** was studied in men with advanced prostate cancer that:

- No longer responded to hormone therapy or surgical treatment to lower testosterone
- Had spread to other parts of the body

This study included 1,717 men. It compared 872 men taking XTANDI with 845 men not taking XTANDI.

These men had not received chemotherapy. All men either continued hormone therapy or had surgery to lower testosterone during the study.

### In this study of mCRPC:

### **XTANDI** slowed advanced prostate cancer progression



- Men taking XTANDI had an 83% lower chance of their cancer progressing compared with men not taking XTANDI during the study. Progression was seen in 118 (14%) men in XTANDI + ADT,\* and 320 (40%) men in ADT alone
  - The median<sup>†</sup> length of time until the cancer got worse<sup>‡</sup> was not reached for men taking XTANDI + ADT vs. 4 months for ADT alone
- Progression was defined as the cancer getting worse, as measured by scans, or if the patient died for any reason

See more study results on the next page.

\*ADT=androgen deprivation therapy (hormone therapy or surgical treatment to lower testosterone).

<sup>†</sup>The median is not the average but the middle of a set of numbers.

\*The length of time from start of the cancer treatment until the cancer got worse, as measured by scans, or if the patient died for any reason.

Results may vary. Talk with your doctor about what this may mean for you.

### **Select Safety Information**

**XTANDI** may cause serious side effects including falls and bone fractures. XTANDI treatment may increase your risk for falls and bone fractures. Falls were not caused by loss of consciousness or seizures. Your doctor will monitor your risks for falls and bone fractures during treatment with XTANDI.



## In this same study in men with mCRPC: XTANDI helped men live longer (Overall Survival)

Men taking XTANDI had a 23% reduction in the risk of death compared with men not taking XTANDI during the study. There were 368 (42%) deaths in XTANDI + ADT vs. 416 (49%) deaths in ADT alone.

The median overall survival<sup>§</sup> was 35 months for the men taking XTANDI + ADT vs. 31 months for ADT alone.

The following numbers are the **median**. The median is not the average but the middle of a set of numbers.



### **XTANDI** delayed the median time before men began chemotherapy

During the study, men taking XTANDI had a 65% reduction in risk of starting a new chemotherapy and also delayed the median time before the men began chemotherapy: 28 months for men taking XTANDI compared with 11 months for men not taking XTANDI.

The following numbers are the **median**. The median is not the average but the middle of a set of numbers.



§The length of time patients are alive after the start of treatment.

### **Select Safety Information**

**XTANDI may cause serious side effects including swallowing problems or choking.** Severe swallowing problems or choking, including life-threatening problems or death can happen in people during treatment with XTANDI, because of the size of the XTANDI capsules and tablets. Swallow each XTANDI capsule or tablet whole with enough water to make sure that you can swallow all of the medicine successfully.





## **XTANDI** in non-metastatic castration-resistant prostate cancer (nmCRPC)

### **XTANDI** was studied in men with advanced prostate cancer that:

- No longer responded to hormone therapy or surgical treatment to lower testosterone
- Had <u>not</u> spread to other parts of the body

This study included 1,401 men. It compared 933 men taking XTANDI with 468 men not taking XTANDI.

These men had not received chemotherapy. All men either continued hormone therapy or had surgery to lower testosterone during the study.

See study results on the next page.

## In this study in men with nmCRPC: XTANDI slowed advanced prostate cancer from spreading



- Men taking XTANDI had a 71% lower chance of their cancer spreading compared with men not taking XTANDI during the study. Spreading was seen in 219 (23.5%) men in XTANDI + ADT,\* and 228 (48.7%) men in ADT alone
  - The median<sup>†</sup> length of time until the cancer spread was 37 months for XTANDI + ADT vs. 15 months for ADT alone
- Cancer was considered spreading as measured by scans or if the person died for any reason

### **Select Safety Information**

**The most common side effects of XTANDI include:** muscle and joint pain, feeling more tired than usual, hot flashes, constipation, decreased appetite, diarrhea, high blood pressure, bleeding problems, falls, bone fractures, and headache.



## In this same study in men with nmCRPC: XTANDI helped men live longer (Overall Survival)

Men taking XTANDI had a 27% reduction in the risk of death compared with men not taking XTANDI during the study. There were 288 (30.9%) deaths in XTANDI + ADT vs. 178 (38%) deaths in ADT alone.

The median overall survival<sup>†</sup> was 67 months for men taking XTANDI vs. 56 months for ADT alone. The following numbers are the **median**. The median is not the average but the middle of a set of numbers.



## In addition, XTANDI delayed the median time before men began their next cancer treatment, including chemo.

During the study, men taking XTANDI had a 79% reduction in risk of starting their next cancer treatment, including chemo. The delay in the median time was 40 months for men taking XTANDI compared with 18 months for men not taking XTANDI.

The following numbers are the **median**. The median is not the average but the middle of a set of numbers.



<sup>\*</sup>ADT=androgen deprivation therapy (hormone therapy or surgical treatment to lower testosterone).

Results may vary. Talk with your doctor about what this may mean for you.

### **Select Safety Information**

XTANDI may cause fertility problems in males, which may affect the ability to father children. Talk to your doctor if you have concerns about fertility.



<sup>&</sup>lt;sup>†</sup>The median is not the average but the middle of a set of numbers.

<sup>\*</sup>The average length of time patients are alive after the start of treatment.



## Non-metastatic castration-sensitive prostate cancer (nmCSPC) with high risk of cancer spreading

### **XTANDI** was studied in men with advanced prostate cancer:

- That had <u>not</u> spread to other parts of the body
- That responds to a hormone therapy to lower testosterone
- Who are at high risk of cancer spreading to other parts of the body

This study included 1,068 men. It compared 355 men taking XTANDI + ADT\* with 355 men taking XTANDI alone and 358 men taking ADT\* alone.

These men had not received chemotherapy. All men had prior surgery or radiation as definitive treatment to their prostate cancer.

See study results on the next page.

### **Select Safety Information**

**XTANDI may cause serious side effects including seizure.** If you take XTANDI, you may be at risk of having a seizure. Avoid activities where a sudden loss of consciousness could seriously harm you or someone else. Tell your doctor right away if you lose consciousness or have a seizure.





### In this study of nmCSPC with high risk of cancer spreading: XTANDI + ADT\* slowed advanced prostate cancer from spreading



XTANDI + ADT

- Men taking XTANDI + ADT had a 58% lower chance of their cancer spreading compared with men taking ADT alone. Cancer spreading was seen in 45 (13%) men in XTANDI + ADT, and 92 (26%) men in ADT alone
  - The median† length of time until the cancer spread† was not reached for either treatment arm
- Cancer was considered spreading as measured by scans or if the person died for any reason

## In the same study in men with nmCSPC with high risk of cancer spreading: XTANDI alone slowed advanced prostate cancer from spreading

37%
LOWER
CHANCE

XTANDI alone

- Men taking XTANDI alone had a 37% lower chance of their cancer spreading compared with men taking ADT\* alone. Cancer spreading was seen in 63 men (18%) in XTANDI alone and 92 men (26%) in ADT alone
  - The median length of time until cancer spread was not reached for either treatment arm
- Cancer was considered spreading as measured by scans or if the person died for any reason

This trial is ongoing to determine the effect on overall survival.

A medication holiday may be recommended by your doctor. This means you may take a break from your treatment. The length of your break will be determined by your doctor.

### **Select Safety Information**

**XTANDI** may cause serious side effects including Posterior Reversible Encephalopathy Syndrome (PRES). If you take XTANDI you may be at risk of developing a condition involving the brain called PRES. Tell your doctor right away if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, reduced eyesight, blurred vision or other visual problems. Your doctor will do a test to check for PRES.



<sup>\*</sup>ADT=androgen deprivation therapy (hormone therapy or surgical treatment to lower testosterone), leuprolide.

<sup>&</sup>lt;sup>†</sup>The median is not the average but the middle of a set of numbers.

<sup>\*</sup>The length of time from start of the cancer treatment until the cancer got worse, as measured by scans, or if the patient died for any reason. Results may vary. Talk with your doctor about what this may mean for you.

### **HOW XTANDI WORKS**

### **How XTANDI works in prostate cancer cells**

XTANDI is an androgen receptor inhibitor. Androgens are a group of hormones that include testosterone. Androgen receptor inhibitors decrease how often androgens like testosterone connect with an androgen receptor, and thereby may slow the growth of prostate cancer tumors and cells.

#### Imagine the inside of a prostate cancer cell as a puzzle

#### Prostate cancer cell

When androgen connects with an androgen receptor, it may cause tumor cells to grow.



### **How XTANDI works**

XTANDI helps to decrease how often androgen can connect with an androgen receptor.

As a result, XTANDI can slow cancer cell growth and the cancer cells may die.



This is how XTANDI was shown to work in laboratory studies. Clinical significance is unknown.

### **Select Safety Information**

**XTANDI may cause serious side effects including allergic reactions.** Allergic reactions have happened in people who take XTANDI. Stop taking XTANDI and get medical help right away if you develop swelling of the face, tongue, lip or throat.



### **TAKING XTANDI**

### Take XTANDI exactly as your doctor tells you

Take your prescribed dose once a day, at the same time each day. Your doctor may change your dose if needed. Your doctor may also change your pill size or stop treatment if you have swallowing problems. Do not change or stop taking your prescribed dose of XTANDI without talking with your doctor first.

- XTANDI can be taken with or without food
- Swallow each XTANDI capsule or tablet whole with enough water to make sure that you can swallow all of the medicine successfully. Do not chew, dissolve, or open the capsules. Do not cut, crush, or chew the tablets. Tell your doctor if you have problems with swallowing or choking on XTANDI because of its pill size
- If you are receiving gonadotropin-releasing hormone (GnRH) therapy, you should continue with this treatment while taking XTANDI unless you have had surgery to lower the amount of testosterone in your body (surgical castration)

If you miss a dose, take your prescribed dose as soon as you remember that day.

**If you forget to take your dose for the whole day,** take your normal dose the next day at your regular time.

Do not take more than your prescribed dose of XTANDI each day.



#### If you take too much XTANDI:

- Call your doctor or
- Go to the nearest emergency room right away

You may have an increased risk of seizure if you take too much XTANDI.



### **TIPS FOR STAYING ON TRACK**

### Use these tips to keep up with taking your medicine as directed by your doctor



Take XTANDI when you do another daily activity, such as after brushing your teeth.



Set an alarm to help you remember to take XTANDI at the same time each day.



Use the pill tracker you may have received with your Starter Kit.



"Having a pill every day fits in my lifestyle. I take XTANDI at night and I have a routine. I don't miss a day."

-Jim, an XTANDI patient

Jim's testimony is accurate at the time of publication but may have changed since.



# HELPFUL TIPS AND HINTS FOR YOUR DAILY HEALTH

- Maintaining a healthy routine
- Tips that may help manage some side effects
- Keeping an open line of communication



### MAINTAINING A HEALTHY ROUTINE

### **Helpful Tips**

It's important to do your best to take care of yourself while living with your disease. Exercising and eating a well-balanced diet can help. The tips below are for patients with cancer in general but have not been studied with XTANDI. Make sure you talk with your healthcare team before deciding if any of these tips may be right for you.



### The benefits of physical activity

Living with your disease doesn't mean you can't be active. Light exercise during cancer treatments has been linked to physical and emotional benefits, such as:

- Improving self-esteem
- Lowering the risk of feeling anxious and depressed
- Lessening symptoms of fatigue
- · Helping control weight

When exercising during treatment, it's important to listen to your body. Be sure to talk with your doctor to create a routine that is safe for you.



#### Adding physical activity to your daily routine

Here are some simple ways to add physical activity to your daily routine.

- Ask a friend or family member to join you
- Walk around your neighborhood
- Rake the leaves
- Work in your garden

- Ride your bike
- Wash your car
- Take the stairs

Remember to talk to your doctor before starting any physical activity routine.



### **MAINTAINING A HEALTHY ROUTINE (cont'd)**

### **Helpful Tips**

It's important to do your best to take care of yourself while living with your disease. Exercising and eating a well-balanced diet can help. The tips below are for patients with cancer in general but have not been studied with XTANDI. Make sure you talk with your healthcare team before deciding if any of these tips may be right for you.



#### The benefits of good nutrition

Food plays an essential role in the way your body functions. That's why it's important to eat foods that are healthy and rich in nutrients. A healthy diet can help you:

- Feel more energetic
- Keep a healthy weight

Eating well can mean something different for everyone, so it's important to work with your doctor or dietitian to create a plan that works for you.



### **Creating a healthy diet**

Getting the right nutrients can help you during treatment:

- Proteins are essential to help you keep a healthier immune system
  - Try: Fish, poultry, nuts and nut butters, or lentils
- Carbohydrates provide your body with energy for physical activity
  - Try: Whole grains (like quinoa or brown rice), fruits, and vegetables
- Water helps your body stay hydrated
  - Try: Drinking about four 8-ounce cups of water per day to stay hydrated

Talk to your doctor to determine the right plan for you.



### TIPS THAT MAY HELP MANAGE SOME SIDE EFFECTS

### The most common side effects of XTANDI and general tips that may help



The most common side effects that men experienced in a clinical trial while taking XTANDI are below. You'll also see information on how to discuss each side effect with your doctor. This information has not been studied with XTANDI.

Remember, the following information does not replace directions from your doctor. Always talk to your healthcare team about side effects and information that may help to address them.

#### Muscle and joint pain

Write down the pain you experience and share it with your healthcare team. Your doctor may recommend physical therapy or medicine to reduce swelling and help with inflammation. They may also suggest light stretching and hot or cold compresses to help reduce the pain.

#### Feeling more tired than usual

Talk to your doctor if you experience fatigue. They may recommend daily exercise or other activities that may help reduce exhaustion. Do not start a new exercise routine without direction from your doctor. If you feel tired during the day, it's okay to rest and take a nap to help increase your energy level.

#### **Hot flashes**

Talk to your doctor if you experience hot flashes. They may recommend you try to lower your body's temperature, along with wearing loose-fitting cotton clothing. Keeping a fan running and your windows open can also help circulate the air throughout your home, which may help.

### **Constipation or decreased appetite**

Tell your doctor if you have constipation or decreased appetite. They may offer you advice about managing your diet, and how you can make adjustments. Work with them to create an eating plan that includes the right amount of nutrients and liquids your body needs. This includes foods you should be eating and foods to avoid.



### TIPS THAT MAY HELP MANAGE SOME SIDE EFFECTS (cont'd)

#### **Diarrhea**

Report diarrhea to your doctor right away. Your doctor may suggest you take over-the-counter anti-diarrheal medicine to help, but it's also important to stay hydrated. Sports drinks, water, and bouillon may be recommended.

### **High blood pressure**

Your doctor may examine you and ask you questions about your medical history and symptoms, as well as listen to your heart. They may recommend you make certain lifestyle changes, such as diet and exercise. Your doctor may also recommend certain medicines to help lower your blood pressure.

#### **Bleeding problems**

XTANDI may increase your risk of bleeding. Be sure to discuss symptoms of bleeding with your doctor. If you suspect internal bleeding or have external bleeding that won't stop, seek immediate medical attention.

#### Falls and bone fractures

If you experience a fall, let your doctor know immediately. Your doctor may need to make adjustments to your treatment plan. Your healthcare team may recommend ways to help make your surroundings safer and find ways to reduce your risk of falling. They may suggest equipment to assist you and exercises to improve your safety and balance. Additionally, wearing supportive footwear can help maintain stability and minimize the chances of falls.

#### Headache

If you encounter persistent headaches, let your doctor know immediately, so they can assess the cause and determine the best course of action to alleviate your pain. While your doctor may recommend specific pain relief medication, activities that reduce stress levels, getting enough sleep, staying hydrated, and reducing caffeine may help prevent headaches.

XTANDI may cause fertility problems in males, which may affect the ability to father children. Talk with your doctor if you have concerns about fertility.

These are not all the possible side effects of XTANDI. For more information, talk with your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.



### **KEEPING AN OPEN LINE OF COMMUNICATION**

### Tips to help improve communication

Good communication is more than telling your healthcare team how you are doing. It means having open and honest conversations. The tips below can help you get started.

### **Communicating with your healthcare team**

- Make a list of questions and concerns before you go to your appointment, including notes on how you're feeling
- Take notes (or ask your caregiver to take notes) when your doctor gives you any instructions or tells you
  important information
- Always make sure you understand what your doctor or nurse is telling you. It may help to repeat back to them in your own words what you are told
- After each appointment, review your notes and focus on what you think are the most important things you
  talked about with your doctor or nurse



Euvon, an XTANDI patient, with wife, Janet

Go to XTANDI.com to watch Euvon share his journey and see how other XTANDI patients are living with advanced prostate cancer.

#### Bring a friend or family member to all of your appointments:

- They can help you remember what your doctor or nurse tells you
- They may also be able to help you give the doctor or nurse more information about how you are doing



### **KEEPING AN OPEN LINE OF COMMUNICATION (cont'd)**

### **Talking with family and friends**

Your family and friends care about you the most. But it may not always be easy to be completely open or honest with them about how you're feeling.

#### Here are some tips to help you talk with family and friends:

- Set aside time to talk with them about what is on your mind
- Practice what you want to say
- Find a time when both of you are open to talking
- After talking, plan additional conversations you may want to have in the future

### **Connecting with other patients**

Support groups can be a good way for you to share your experiences and to hear from other men about theirs. Talking and listening to other men can help you feel supported and keep you motivated. It can also help you feel more comfortable being open about the way you're feeling. Visit XTANDI.com to learn more.



Don't be afraid to ask questions. Remember, your healthcare team is here to support you. Make a list before each appointment so you remember what you want to ask or say. In addition, you can find a helpful Doctor Discussion Guide at XTANDI.com.



# INDICATION AND IMPORTANT SAFETY INFORMATION

- What is XTANDI?
- Important Safety Information



### INDICATION AND IMPORTANT SAFETY INFORMATION

#### What is XTANDI?

XTANDI is a prescription medicine used to treat men with prostate cancer that:

- no longer responds to a hormone therapy or surgical treatment to lower testosterone OR
- has spread to other parts of the body and responds to a hormone therapy or surgical treatment to lower testosterone
   OR
- has not spread to other parts of the body and responds to a hormone therapy or surgical treatment to lower testosterone, and who are at high risk of cancer spreading to other parts of the body

It is not known if XTANDI is safe and effective in females or children.

#### WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING XTANDI?

Tell your doctor about all your medical conditions, including if you:



Have a history of seizures, brain injury, stroke, or brain tumors.



Have a history of heart disease, have high blood pressure, or have abnormal amounts of fat or cholesterol in your blood (dyslipidemia).











### Are pregnant or plan to become pregnant.

XTANDI can cause harm to your unborn baby and loss of pregnancy (miscarriage).

### Have a partner who is pregnant or may become pregnant.

- Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment with XTANDI and for 3 months after the last dose.
- Males must use a condom during sex with a pregnant female.

### Are breastfeeding or plan to breastfeed.

It is not known if XTANDI passes into your breast milk.

#### Take other medicines.

XTANDI may affect the way other medicines work, and other medicines may affect how XTANDI works. These include prescription and over-the-counter medicines, vitamins, and herbal supplements. Do not start or stop any medicine without talking to your doctor.



#### **HOW SHOULD I TAKE XTANDI?**



### Take XTANDI exactly as your doctor tells you.

Take your prescribed dose once a day, at the same time each day. XTANDI can be taken with or without food. Swallow XTANDI capsules or tablets whole with enough water to make sure that you can swallow all of the medicine successfully. **Do not** chew, dissolve, or open the capsules. **Do not** cut, crush or chew the tablets. Your doctor may change your dose if needed. Your doctor may also change your pill size or stop treatment if you have swallowing problems.



Do not change or stop taking your prescribed dose of XTANDI without talking with your doctor first.



If you are receiving gonadotropin-releasing hormone (GnRH) therapy, you should continue with this treatment while taking XTANDI unless you have had surgery to lower the amount of testosterone in your body (surgical castration).





### If you miss a dose of XTANDI:

Take your prescribed dose as soon as you remember that day. If you miss your daily dose, take your prescribed dose at your regular time the next day. Do not take more than your prescribed dose of XTANDI each day.

### If you take too much XTANDI:

Call your doctor or go to the nearest emergency room right away. You may have an increased risk of seizure if you take too much XTANDI.



#### WHAT ARE THE POSSIBLE SIDE EFFECTS OF XTANDI?

### **XTANDI** may cause serious side effects including:



#### Seizure

If you take XTANDI, you may be at risk of having a seizure. Avoid activities where a sudden loss of consciousness could seriously harm you or someone else. Tell your doctor right away if you lose consciousness or have a seizure.



### **Posterior Reversible Encephalopathy Syndrome (PRES)**

If you take XTANDI you may be at risk of developing a condition involving the brain called PRES. Tell your doctor right away if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, reduced eyesight, blurred vision or other visual problems. Your doctor will do a test to check for PRES.



### **Allergic Reactions**

Allergic reactions have happened in people who take XTANDI. Stop taking XTANDI and get medical help right away if you develop swelling of the face, tongue, lip or throat.





#### **Heart Disease**

Blockage of the arteries in the heart (ischemic heart disease) that can lead to death has happened in some people during treatment with XTANDI. Your doctor will monitor you for signs and symptoms of heart problems during your treatment. Call your doctor or go to the emergency room right away if you get chest pain or discomfort at rest or with activity or shortness of breath during your treatment with XTANDI.



#### **Falls and Bone Fractures**

XTANDI treatment may increase your risk for falls and bone fractures. Falls were not caused by loss of consciousness or seizures. Your doctor will monitor your risks for falls and bone fractures during treatment with XTANDI.



### **Swallowing Problems or Choking**

Severe swallowing problems or choking, including life-threatening problems or death can happen in people during treatment with XTANDI, because of the size of the XTANDI capsules and tablets. Swallow each XTANDI capsule or tablet whole with enough water to make sure that you can swallow all of the medicine successfully.

Your doctor will stop treatment with XTANDI if you have serious side effects.



#### WHAT ARE THE POSSIBLE SIDE EFFECTS OF XTANDI?



### The most common side effects of XTANDI include:

- Muscle and joint pain
- Feeling more tired than usual
- Hot flashes
- Constipation
- · Decreased appetite
- Diarrhea
- High blood pressure
- Bleeding problems
- Falls
- Bone fractures
- Headache

XTANDI may cause fertility problems in males, which may affect the ability to father children. Talk to your doctor if you have concerns about fertility.

These are not all the possible side effects of XTANDI. For more information, talk to your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or <a href="www.fda.gov/medwatch">www.fda.gov/medwatch</a>.



### **SUPPORT FOR XTANDI**

- How to get XTANDI
- XTANDI Support Solutions®
- Questions to ask at your next appointment



### **HOW TO GET XTANDI**

### There are 2 ways to get XTANDI

It's important to know that XTANDI is not available at your local pharmacy.

Specialty pharmacy

In most cases, your doctor will send your XTANDI prescription to a specialty pharmacy. A specialty pharmacy fills prescriptions for medicines that you can't get at your regular pharmacy.

One benefit of getting XTANDI from a specialty pharmacy is that your medicine will be mailed right to your home. The specialty pharmacy will call you to arrange the delivery of your medicine.

Pharmacy in your doctor's office
In some cases, your doctor's office may have its own pharmacy that can fill your XTANDI prescription.



**XTANDI Support Solutions® helps eligible patients find ways to pay for XTANDI** 

Our dedicated access specialists are here to help. Call 1-855-8XTANDI (1-855-898-2634).



### **HOW TO GET XTANDI (cont'd)**

### **Getting XTANDI from a specialty pharmacy**

Here's how the process typically works, plus a few tips to help ensure it goes as smoothly as possible.



At your doctor's office: A member of your healthcare team will fill out the insurance forms with you. They will send your prescription to a specialty pharmacy or XTANDI Support Solutions® to help with the process.

Tip At your appointment, confirm that your forms are complete and correct.

A few days after your appointment: The specialty pharmacy will call you about your out-of-pocket costs and arrange the delivery of your medicine. You may also receive a call from XTANDI Support Solutions if there are any questions about your insurance forms.

Reach out to your doctor if you haven't heard from your specialty pharmacy within a few days.



### **HOW TO GET XTANDI (cont'd)**



When it's time for delivery: XTANDI may be delivered right to your home.

When it's time for a refill: Your specialty pharmacy will call you to arrange a refill.

Tip If you haven't received your medicine, call your doctor or specialty pharmacy.

Tip Contact your specialty pharmacy
2 weeks before your medicine is
going to run out if you have not
heard from them.



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### **XTANDI SUPPORT SOLUTIONS®**



XTANDI Support Solutions® offers resources based on your specific needs, including help for eligible patients to get XTANDI based on their insurance coverage. Call us today to get personalized support at **1-855-8XTANDI** (**1-855-898-2634**). We're available Monday through Friday, 8 AM to 8 PM ET.



### **Help getting XTANDI**

Our dedicated access specialists will work closely with you and your healthcare team to help make the distribution process with the specialty pharmacy as simple as possible.

#### We can help with:

- Making sure your healthcare team has the paperwork they need to submit to your insurance company
- Arranging for the delivery of XTANDI through a specialty pharmacy to help you start your medicine as soon as possible



### XTANDI SUPPORT SOLUTIONS® (cont'd)

### **Help paying for XTANDI**

Call XTANDI Support Solutions® at **1-855-8XTANDI** (**1-855-898-2634**) to speak with a dedicated specialist who can see if you are eligible for programs that may help you pay for XTANDI (enzalutamide).

#### If you're commercially insured:



The XTANDI Patient Savings Program\* allows eligible patients with commercial prescription insurance to pay as little as \$0 per prescription.

Enroll at **XTANDIcopayenroll.com**.

#### If you're on Medicare Part D:

We can provide information about other resources that may be able to help.<sup>†</sup>

#### If you're uninsured:

The Astellas Patient Assistance Program provides XTANDI at no cost to patients who meet the program eligibility requirements.† All patients in this program who qualify receive their XTANDI prescription at no cost.

\*By enrolling in the XTANDI Patient Savings Program ("Program"), the patient acknowledges that they currently meet the eligibility criteria and will comply with the following terms and conditions: The Program is for eligible patients with commercial prescription insurance coverage for XTANDI (enzalutamide) and is good for use only with a valid prescription for the XTANDI tablet formulation. The Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program, including, but not limited to, Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program. Patients who move from commercial insurance to federal or state health insurance will no longer be eligible, and agree to notify the Program of any such change. Patients agree not to seek reimbursement from any health insurance or third party for all or any part of the benefit received by the patient through the Program. This offer is not conditioned on any past, present, or future purchase of XTANDI. This offer is not transferrable and cannot be combined with any other offer, free trial, prescription savings card, or discount. The full value of the Program benefits is intended to pass entirely to the eligible patient. This offer is not health insurance and is only valid for patients in the 50 United States, Washington DC, Puerto Rico, Guam and Virgin Islands. This offer is not valid for cash paying patients. This Program is void where prohibited by law. No membership fees. It is illegal to sell, purchase, trade, counterfeit, duplicate, or reproduce, or offer to sell, purchase, trade, counterfeit, duplicate or reproduce the card. This offer will be accepted only at participating pharmacies. Certain rules and restrictions apply. Astellas reserves the right to revoke, rescind, or amend this offer without notice.

The Program has a maximum copay assistance limit of \$7,000 per calendar year. After the annual maximum on copay assistance is reached, patient will be responsible for the remaining out-of-pocket costs for XTANDI. Astellas may reduce or discontinue the copay assistance available under the Program if it determines an enrolled patient is subject to a program offered by a third-party payer or pharmacy benefit manager, or an agent of either, that adjusts patients' out-of-pocket cost-sharing obligations based on the copay assistance provided by this Program, or excludes the copay assistance provided under this Program from counting towards an enrolled patient's out-of-pocket cost-sharing obligations ("maximizer" or "accumulator" program). The Program uses advanced logic to identify whether a claim for an enrolled patient is subject to a "maximizer" or "accumulator" program. Unless prohibited by law, Astellas may reduce the cost-sharing assistance available under the Program to a per claim maximum of \$25 if it determines a claim for an enrolled patient is subject to a "maximizer" or "accumulator" program.

†XTANDI Support Solutions® has no control over the decisions made by and does not guarantee support from independent third parties.

<sup>&</sup>lt;sup>†</sup>Subject to eligibility. Void where prohibited by law.





### **QUESTIONS TO ASK AT YOUR NEXT APPOINTMENT**



Your health is a team effort. You and your doctor make decisions about your health plan. Here are some important questions you may want to ask your doctor.

### **Can XTANDI help patients:**

- Live longer?
- Delay the progression or spread of cancer?
- Lower the chances of having to start a new chemotherapy regimen?

### When is the right time to start XTANDI?

• Are there benefits of starting XTANDI now?

### What are the potential side effects of XTANDI?

### Will my insurance cover XTANDI?

• Can I get assistance paying for XTANDI?

### How do I take XTANDI? How often do I need to take XTANDI?

Do I need to take XTANDI with food?

How extensively has XTANDI been studied, tested, and used in patients?











